No. 92-1338

FILED
FEB 3 1993
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

DIETARY SUPPLEMENT COALITION, INC. and THE HEALTH HAUS, INC.,

Petitioners,

vs.

DONNA E. SHALALA, Secretary of Health and Human Services, and DAVID A. KESSLER, Commissioner of Food and Drugs,

Respondents.

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

I. SCOTT BASS
PIPER & MARBURY
31 West 52nd Street
New York, New York 10019
(212) 261-2000

Counsel of Record for Petitioners

Of Counsel:
CHARLES J. RAUBICHECK
PIPER & MARBURY
New York, New York 10019

February 3, 1993

QUESTIONS PRESENTED FOR REVIEW

1. Does the Food and Drug Administration's institution of seizure actions, alleging the seized products to be violative of the Federal Food, Drug, and Cosmetic Act as a matter of law, constitute final agency action entitling other persons who distribute the same products to commence an action for a declaratory judgment that the substance does not violate said Act? The Ninth Circuit has answered in the negative, while the First and Second Circuits have explicitly ruled to the contrary.

2. When an agency of the United States Government institutes a seizure action against a product claiming a violation as a matter of law, thereby subjecting all manufacturers of that

product to potential civil enforcement and criminal prosecution for the continued sale thereof, may that agency then insulate itself from a declaratory judgment action challenging the product's legal status, asserting that no final agency action had transpired?

LIST OF PARTIES

The parties to the proceedings below were appellants Dietary Supplement Coalition, Inc. and The Health Haus, Inc., and appellees Louis W. Sullivan, Secretary of Health and Human Services, and David A. Kessler, Commissioner of Food and Drugs.

On this petition, the same appellants are the petitioners. Respondents are the Secretary of Health and Human Services and the Commissioner of Food and Drugs. Since Dr. Sullivan is no longer Secretary of Health and Human Services, his successor, Donna E. Shalala, has been substituted as the principal respondent on this petition.

Pursuant to Rule 29.1 of this Court, petitioner Dietary Supplement Coalition, Inc. is a non-profit New York corporation

having no parent or subsidiary corporation, and petitioner The Health Haus, Inc. is an Oregon corporation having no parent or subsidiary corporation.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

OPINIONS BELOW 1

JURISDICTION 2

STATUTES 4

STATEMENT OF THE CASE 6

REASONS FOR GRANTING THE WRIT 14

I. **The Ninth Circuit's ruling that FDA seizure actions do not constitute final agency action warranting judicial review conflicts with decisions of two other Circuits and is erroneous as a matter of law** 14

II. The decision below that a legal issue raised in a Federal enforcement action is not reviewable agency action vitiates a fundamental right vested by Congress in U.S. citizens under the Declaratory Judgments Act 25

CONCLUSION 31

APPENDIX

DIETARY SUPPLEMENT COALITION ET AL., V. LOUIS W. SULLIVAN, M.D., SECRETARY OF HEALTH AND HUMAN SERVICES, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, AND FOOD AND DRUG ADMINISTRATION (9TH CIR. NOVEMBER 5, 1992) A1-A10

DIETARY SUPPLEMENT COALITION ET AL., V. LOUIS W. SULLIVAN, M.D., SECRETARY OF HEALTH AND HUMAN SERVICES, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, AND FOOD AND DRUG ADMINISTRATION, 796 F. SUPP. 441 (D. OR. 1991) A11-A35

UNITED STATES OF AMERICA V. TWO PLASTIC DRUMS...VIPONTE BLACK CURRANT OIL, 1993 U.S. APP. LEXIS 1275 (7TH CIR. JAN. 27, 1993) . A-27-A51

TABLE OF AUTHORITIES

CASES — PAGE

Abbott Laboratories, Inc. v. Gardner, 387 U.S. 136 (1967) 10, 18, 19, 24, 26, 27

Assiniboine and Sioux Tribes of Ft. Peck Indian Reservation v. Board of Oil and Gas Conservation of Montana, 792 F.2d 782 (9th Cir. 1986) 30

Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986) 26

Ciba-Geigy Corp. v. EPA, 801 F.2d 430 (D.C. Cir. 1986) . . 27, 30

Columbia Broadcasting System v. United States, 316 U.S. 407 (1942) . 18

Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, reh'g denied, 340 U.S. 857 (1950) 28

Franklin Fed. Savings Bank v. Director, Office of Thrift Supervision, 927 F.2d 1332 (6th Cir. 1991) 27

Frozen Food Express v. United States, 351 U.S. 40 (1956) 18, 28

Independent Bankers Ass'n v. Smith, 534 F.2d 921 (D.C. Cir.), cert. denied, 429 U.S. 862 (1976) . . 30

Lujan v. National Wildlife Fed'n, 497 U.S. 871, 110 S. Ct. 3177 (1990) 22

Natick Paperboard Corp. v. Weinberger, 498 F.2d 125 (1st Cir. 1974), cert. denied, 429 U.S. 819 (1976) . 14, 15, 16, 19, 27

National Automatic Laundry & Cleaning Service v. Schulz, 443 F.2d 689 (D.C. Cir. 1971) 30

Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795 (2d Cir. 1980) . 15, 16, 19

Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967) 18

United States v. An Article of Food ... FoodScience Laboratories, Inc., 678 F.2d 735 (7th Cir. 1982) 23

United States v. Bioenergy Nutrients, Inc....Coenzyme Q10, Civ. 89-M-1095 (D. Co., filed June 27, 1989) 8

United States v. Storer Broadcasting Co., 351 U.S. 192 (1956) 18

United States v. 42/30 Tablet Bottles...Coenzyme Q10, 779 F. Supp. 253 (E.D.N.Y. 1991) 8, 11, 23

United States v. 4 Cans... Master Liquid, 127 F. Supp. 243 (D. Iowa 1955) 8

United States v. 14/105 Pound Bags...Mineral Compound, 118 F. Supp. 837 (D. Idaho 1953) . . . 8

United States v. Fausto, 484 U.S. 439, reh'g denied, 485 U.S. 972 (1988) 26

United States v. 29 Cartons... Oakmont Investment Co., 792 F. Supp. 139 (D. Mass. 1992) . . 23

United States v. Two Plastic Drums...Viponte Black Currant Oil, 1993 U.S. App. Lexis 1275 (7th Cir. Jan. 27, 1993) 23

United States v. Undetermined Quantities... Blue-Green Algae, No. 83-1180-FR (D. Or. Nov. 8, 1984) 23

United States v. Vitality Systems, Inc., No. 89-1009-DA (D. Or. Aug. 6, 1991) 23

STATUTES

21 U.S.C. §321(s) 20, 21, 23

21 U.S.C. §331, 332 9

21 U.S.C. §334(a)(1) 8

28 U.S.C. §2201(a) 25

OPINIONS BELOW

The opinion and judgment of the Court of Appeals for the Ninth Circuit, dated November 5, 1992, has not yet been reported; it is reprinted in the Appendix hereto. (Appendix, A1-A10). The district court's decision upon which the Ninth Circuit's opinion is based is reported at 796 F. Supp. 441 (D. Or. 1991), and is also reprinted in the Appendix. (Appendix, A11-A35).

JURISDICTION

Invoking jurisdiction under 28 U.S.C. §§1331 and 1337, petitioners sought a declaratory judgment in the district court pursuant to 28 U.S.C. §§2201 and 2202. The district court issued a memorandum decision and judgment dismissing the action upon respondents' motion for lack of ripeness for judicial review on November 5, 1992.

On petitioners' appeal, the United States Court of Appeals for the Ninth Circuit entered an opinion and judgment affirming the district court's judgment.

The jurisdiction of this Court to review the judgment of the Court of

Appeals for the Ninth Circuit is invoked under 28 U.S.C. §1254(1).

STATUTES

28 U.S.C. §2201(a); Declaratory Judgments: Creation of remedy.

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of Canadian merchandise, as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

21 U.S.C. §321(s); Federal Food, Drug, and Cosmetic Act: Definitions; Generally.

The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing,

processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use....

21 U.S.C. §334(a)(1); Federal Food, Drug, and Cosmetic Act:
Seizures - Grounds and Jurisdiction.

Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found...

STATEMENT OF THE CASE

Co-enzyme Q10 ("CoQ10") is a nutrient widely distributed by many companies both in the United States and abroad. It is a building block of vitamins, much as amino acids are the building blocks of protein. CoQ10 is available in dietary supplement form -i.e., in capsules or tablets, either alone or in conjunction with other nutrients. The product is consumed for its nutrient value and is labeled and taken as a supplement to a regular diet by many Americans.

There are various member companies of petitioner Dietary Supplement Coalition, Inc. ("DSC"), a trade association based in Farmingdale, New York, who manufacture and/or distribute CoQ10 dietary

supplements. Petitioner The Health Haus, Inc. of Portland, Oregon is a retail store that sells several brands of CoQ10 supplements.

Respondents Shalala and Kessler[1] have taken the position that CoQ10 is an "unapproved food additive" rendering it an adulterated food and violative of the FDCA. As a result of this determination, FDA has instituted seizure actions against CoQ10 supplements distributed by several member companies of petitioner DSC, praying for condemnation and destruction

[1] Respondent Shalala is authorized to administer the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301 et seq., as amended (hereinafter "the FDCA"), through respondent Kessler, Commissioner of the Federal Food and Drug Administration ("FDA"). For convenience, respondents will hereinafter be referred to collectively as "FDA."

of such products.[2] A judgment in a given seizure action is res judicata against all other subsequent shipments of the same product, effectively permitting FDA to remove the product from the market upon prevailing in a single seizure by virtue of the threat of multiple seizures.[3]

[2] United States v. Bioenergy Nutrients, Inc. . . . Coenzyme Q10, Civ. 89-M-1095 (D. Co., filed June 27, 1989); United States v. 42/30 Tablet Bottles . . . Coenzyme Q10, 779 F. Supp. 253 (E.D.N.Y. 1991). A seizure action is an in rem proceeding brought by FDA in a Federal district court, seeking an order of condemnation and destruction of an article of food, drug, device or cosmetic because it allegedly violates some provision of the FDCA. 21 U.S.C. §334(a)(1).

[3] 21 U.S.C. §334(a)(1); United States v. 4 Cans ... Master Liquid, 127 F. Supp. 243 (D. Iowa 1944); United States v. 14/ 105 Pound Bags ... Mineral Compound, 118 F. Supp. 837 (D. Idaho 1953).

A violation of the FDCA carries both civil sanctions and criminal penalties. Manufacturers and distributors of CoQ10 are subject not only to civil seizure actions (and the attendant condemnation and destruction of up to millions of dollars of the seized articles), but also to injunctions and to criminal prosecutions.[4]

Petitioners commenced this action for declaratory judgment on February 7, 1991 in the United States District Court for the District of Oregon to obtain a declaration that CoQ10 in capsule or tablet form is a "food" as opposed to a

[4] 21 U.S.C. §§331, 332. All violations of the FDCA are subject to both civil and criminal remedies. FDA has enforcement discretion as to which type of proceeding to bring for alleged FDCA violations.

"food additive" within the meaning of the FDCA, which may be distributed in interstate commerce without violating the FDCA. FDA moved to dismiss the action on the grounds that it presented no issue ripe for judicial review, and that petitioners had failed to exhaust their administrative remedies. On July 11, 1991, the district court issued an opinion and order dismissing the action for lack of subject matter jurisdiction, primarily because the FDA had allegedly not made a final determination as to the legal status of CoQ10.

Thereafter, petitioners appealed the district court's decision to the Court of Appeals for the Ninth Circuit. While purporting to apply this Court's seminal holding in Abbott Laboratories, Inc. v.

Gardner, 387 U.S. 136 (1967), to the ripeness issue (Appendix, A5), the Ninth Circuit nonetheless affirmed the district court's decision in an opinion and judgment filed November 5, 1992. The court held that petitioners' declaratory judgment claim was not ripe for review for want of final agency action, because the FDA had made no "general statement regarding the general use of CoQ10." (Appendix, A7).[5] In so holding, the Ninth

[5] The court adhered to this rationale despite being presented with the following deposition testimony by a responsible FDA official in one of the CoQ10 seizures:

> Q: To your knowledge, does FDA have to go through any further steps to determine whether it considers CoQ10 an unsafe food additive?
>
> A: No.
>
> (Deposition of Gerad L. McCowin in United States v. 42/30 Tablet Bottles...Coenzyme Q10, supra,

Circuit explicitly conceded that two other Circuits have held FDA seizure actions to be final agency action rendering a legal issue raised therein ripe for judicial review. Id.

The Ninth Circuit further ruled that the petitioners' declaratory claim lacked ripeness because the regulatory status of CoQ10 is not solely a legal issue, notwithstanding that FDA had claimed in the seizure actions it had initiated that CoQ10 is an unsafe food additive as a matter of law. (Appendix, A8).

Aug. 28, 1991).

While the Ninth Circuit chose to disregard this testimony because it took place after the record before the district court in this case had closed (Appendix, A5), the court mentioned the testimony twice in its opinion (Appendix, A5, A8), and FDA counsel conceded at oral argument that the testimony was accurate.

Finally, the Ninth Circuit ruled that its position on the finality issue disposed of petitioners' claims that (a) they suffered undue hardship from the potential threat of enforcement actions against their CoQ10 supplements, and (b) exhaustion of further administrative remedies was futile in light of FDA's adamant position evidenced by the seizure actions. (Appendix, A9).

REASONS FOR GRANTING THE WRIT

I. The Ninth Circuit's ruling that FDA seizure actions do not constitute final agency action warranting judicial review conflicts with decisions of two other Circuits and is erroneous as a matter of law.

The Ninth Circuit's holding is squarely in conflict with the holdings of the Courts of Appeals of both the First and Second Circuits that such seizures are sufficiently final to permit review.

In Natick Paperboard Corp. v. Weinberger, 498 F.2d 125, 129 (1st Cir. 1974), cert. denied, 429 U.S. 819 (1976), the Court of Appeals for the First Circuit held that FDA's mere threat of seizures constituted final agency action warranting an action for declaratory judgment to review FDA's assertion that paper food-

packaging materials containing PCB's in excess of a particular tolerance level were unsafe food additives. In Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 799 (2d Cir. 1980), the Second Circuit Court of Appeals held that FDA's seizure of an alleged new drug was final agency action permitting a separate declaratory judgment action to review this allegation.

The Ninth Circuit openly acknowledged the conflict of its ruling with the First and Second Circuit decisions in Natick and Premo. However, the Court attempted to distinguish these decisions by stating that "in both cases the agency had taken an explicit position as to the product at issue." (Appendix, A7). This is squarely contradicted by the facts. In Natick, FDA

announced that until it reached a final decision on the merits, it would seize paper food packaging materials that exceeded the tolerance. Natick, 498 F.2d at 126. In Premo, FDA had not made a final determination on the new drug status of Premo's product but had asked for further data, and then seized the product because Premo continued to market it. Premo, 629 F.2d at 679.

Moreover, the Ninth Circuit's assertion is a distinction without a difference. The substance CoQ10 in petitioners' complaint is identical to the substance CoQ10 alleged to be an unsafe food additive in the seizure actions brought by FDA. Petitioner DSC has two member companies whose CoQ10 supplements

were actually the subject of those FDA seizures.

Contrary to the Ninth Circuit's assertion, FDA has made a "general statement" regarding CoQ10 by the very act of instituting seizures upon the charge that the substance is an unsafe food additive as a matter of law. Moreover, the Court's further assertion that "seizures in themselves do not amount to a final agency position on all uses of CoQ10" circumvents the central issue in this case. The substance CoQ10 is the target of FDA's enforcement program against CoQ10; the target is not a particular use of this substance. In fact, the use of all CoQ10 supplements is the same - as nutrients to supplement the daily diet of consumers.

If this Court's ripeness jurisprudence, definitively articulated in Abbott v. Gardner (likewise a case involving FDA enforcement), is to be uniformly followed by lower Federal courts, the Circuit split on this issue must be resolved, and the Ninth Circuit's contradictory decision must be reversed. Abbott instructs that an action for declaratory judgment is ripe for judicial review if it involves final agency action presenting a legal issue, and if hardship to the plaintiff would ensue if review were withheld. 387 U.S. at 149.[6] In Abbott, this Court held that an FDA

[6] Accord: Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967); Frozen Food Express v. United States, 351 U.S. 40 (1956); United States v. Storer Broadcasting Co., 351 U.S. 192 (1956); Columbia Broadcasting System v. United States, 316 U.S. 407 (1942).

regulation which allegedly created a drug advertising requirement beyond the authority of FDA under the FDCA was ripe for review because it was a final rule involving a legal issue, the mere existence of which created undue hardship to the plaintiffs - 37 pharmaceutical manufacturers and their trade association - who faced an immediate and practical impact -- serious FDA civil and criminal sanctions affecting running of their day-to-day businesses -- if they did not accede to FDA's interpretation. 387 U.S. at 148-153. The First and Second Circuits have held seizure actions to be, a fortiori, at least the equivalent of a regulation for finality and hardship purposes under the Abbott test. Natick, 498 F.2d at 128; Premo, 695 F.2d at 801.

CoQ10 supplement manufacturers and distributors face the hardship of further FDA seizures or FDA criminal enforcement action imperiling their day-to-day businesses unless they accede to FDA's claim and stop selling the products. A more compelling case in which to apply Abbott would be difficult to imagine.

FDA's seizures of CoQ10 supplements alleging them to be unsafe food additives as a matter of law are plainly FDA's final pronouncement on the status of CoQ10 supplements under the FDCA. They present a legal issue - whether CoQ10 is a food additive within the meaning of the statutory definition of that term in the FDCA, 21 U.S.C. §321(s).

FDA's sophistic assertion that the CoQ10 food additive issue is a mixed legal-factual determination flatly contradicts the position FDA has taken in the seizures themselves - that CoQ10 is an unsafe food additive as a matter of law within the meaning of 21 U.S.C. §321(s). The Ninth Circuit's acceptance of this argument is based upon an erroneous finding that the CoQ10 seizures involved "different facts." (Appendix, A8)[7] Significantly, FDA has not claimed that there is any difference in the CoQ10 substance in any of the seizures. The

[7] This finding presumably infers that the seized CoQ10 supplements had particular binders or excipients or contained additional nutrients, which is immaterial. The substance CoQ10 itself was the reason FDA brought the seizures, and the legal status of this substance, as a single-entity or combined with other nutrients, is the precise gravamen of petitioners' complaint for declaratory relief.

Ninth Circuit apparently bought FDA's untenable argument that the CoQ10 seizures involved different products solely because they involved CoQ10 products of different manufacturers.

As this Court has stated, an issue is ripe for review where "the scope of the controversy has been reduced to more manageable proportions and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens him." Lujan v. National Wildlife Fed'n, 497 U.S. 871, 110 S. Ct. 3177, 3190 (1990). There could be no more concrete action creating a situation threatening petitioners than FDA's seizures of CoQ10.

Petitioners' challenge has a strong probability of success on the merits regarding supplements containing CoQ10 as the sole nutrient ingredient. Several recent decisions have held that single-entity nutrients are not food additives as defined by 21 U.S.C. §321(s), since a single nutrient is not an additive, but is the food itself.[8] United States v. Two

[8] See also United States v. 29 Cartons . . . Oakmont Investment Co., 792 F. Supp. 139 (D. Mass. 1992); United States v. Vitality Systems, Inc., No. 89-1009-DA (D. Or. Aug. 6, 1991); United States v. Undetermined Quantities...Blue-Green Algae, No. 83-1180-FR (D. Or. Nov. 8, 1984). But see United States v. An Article of Food...FoodScience Laboratories, Inc., 678 F.2d 735 (7th Cir. 1982); United States v. 42/30 Tablet Bottles...Coenzyme Q10, supra note 2, at 7 (a nutrient is a food additive in supplements containing two or more nutrients). This case sought a declaration as to CoQ10 in any form; the prior seizures involved both CoQ10 as a single ingredient in a capsule and as an ingredient in multi-nutrient products.

Plastic Drums . . . Viponte Black Current Oil, 1993 U.S. App. Lexis 1275 (7th Cir. Jan. 27, 1993) (slip opinion in Appendix, A36-A51).

Accordingly, this Court is urged to grant a writ of certiorari to resolve this patent conflict among the Circuits, and to affirm that Abbott authorizes declaratory review when FDA has espoused a legal position via the commencement of seizures that affect the daily fortunes of all interested persons who market the same product.

II. The decision below that a legal issue raised in a Federal enforcement action is not reviewable agency action vitiates a fundamental right vested by Congress in U. S. citizens under the Declaratory Judgments Act.

Unless the Ninth Circuit's decision is reversed, manufacturers and distributors of all products regulated by FDA (and of all products regulated by Federal departments and agencies having court enforcement powers) will be denied a fundamental right vested by Congress under the Declaratory Judgments Act in all U. S. citizens, namely, to have access to the Federal courts seeking a declaration on legal issues directly affecting their rights to sell their products in interstate commerce. 28 U.S.C. §2201(a). Such preclusion will be controlling within the Ninth Circuit; it will also have a

chilling effect on companies in other Circuits, who will be discouraged from pursuing appropriate declaratory proceedings if this ruling is allowed to stand. Most importantly, this ruling would allow agencies to hold companies' economic fortunes hostage while they pursue enforcement actions immunized from effective legal challenge.

This Court has consistently held that: "...[j]udicial review of a final agency action will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress," Abbott, 387 U.S. at 139, a principle that applies in all regulatory contexts. See, e.g., United States v. Fausto, 484 U.S. 439, 452, reh'g denied, 485 U.S. 972 (1988); Bowen v. Michigan Academy of

Family Physicians, 476 U.S. 667, 670 (1986). Moreover, this Court has long recognized that the hazard of doing business under the threat of Federal enforcement activity justifies the right to maintain declaratory claims on relevant legal issues. Abbott, 387 U.S. at 153. Lower Federal courts have continually adhered to this precept. See, e.g., Franklin Fed. Savings Bank v. Director, Office of Thrift Supervision, 927 F.2d 1332, 1337 (6th Cir. 1991), Ciba-Geigy Corp. v. Environmental Protection Agency, 801 F.2d 430, 435-436 (D.C. Cir. 1986).

The First Circuit in Natick explicitly reaffirmed this principle in the FDA seizure context, properly ruling that while FDA has the discretion to bring seizures, this Court's holdings in Abbott

and Frozen Food Express (supra note 6) mandate that simultaneous declaratory judgment actions by potentially affected interested persons be allowed to proceed. 498 F. 2d at 128.[9]

It is imperative for this Court to resolve the critical question of whether FDA-regulated companies can properly be cut off from access to declaratory relief in the Federal courts on legal issues raised by FDA in seizure actions against

[9] Such other persons cannot intervene in seizure actions already being defended, since seizures are actions in rem allowing only a single claimant-owner to defend on behalf of the seized articles. 21 U.S.C. §334(a)(1). Thus, the rule of Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, reh'g denied, 340 U.S. 857 (1950), that legal arguments may be raised in seizure actions themselves, is in-apposite to situations such as that presented here, where petitioners lack standing to intervene.

similarly-situated companies marketing the same product or substance. To allow the existing conflict among the Circuits to remain puts in jeopardy the ongoing operations of numerous companies where FDA has staked out a legal position with which the companies disagrees. At its extreme, the conflict would allow FDA to prosecute a company criminally after having avoided an earlier declaratory challenge on the pretext that the relevant agency legal position is not "final." Manifestly, this issue cuts across other regulatory

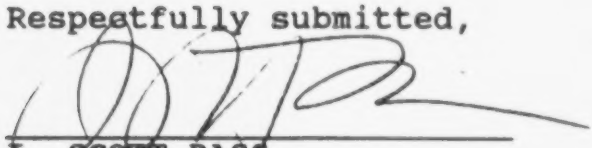
schemes.[10] This Court's guidance is truly needed and warranted.

[10] See, e.g., Ciba-Geigy Corp, supra; Assiniboine and Sioux Tribes v. Board of Oil and Gas Conservation of Montana, 792 F.2d 782 (9th Cir. 1986); Independent Bankers Ass'n v. Smith, 534 F.2d 921 (D.C. Cir.), cert. denied, 429 U.S. 862 (1976); National Automatic Laundry & Cleaners Council v. Schulz, 443 F.2d 689 (D.C. Cir. 1971).

CONCLUSION

For the foregoing reascns, this petition for certiorari should be granted.

Respectfully submitted,



I. SCOTT BASS
Piper & Marbury
31 West 52nd Street
New York, New York 10019
(212) 261-200

Counsel of Record
for Petitioners

Of Counsel:

Charles J. Raubicheck
Piper & Marbury
New York, New York 10019

February 3, 1992

APPENDIX

FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

DIETARY SUPPLEMENTAL COALITION, INC.; THE HEALTH HAUS, INC.,
Plaintiffs-Appellants,

v.

LOUIS W. SULLIVAN, M.D.; DAVID A. KESSLER, Commissioner of Food and Drug Administration,
Defendants-Appellees.

No. 91-36013
D.C. No. CV-91-00126-JAR
OPINION

Appeal from the United States District Court
for the District of Oregon
James A. Redden, District Judge, Presiding

Argued and Submitted
September 18, 1992—Portland, Oregon

Filed November 5, 1992

Before: Robert R. Beezer, John T. Noonan, Jr., and Stephen S. Trott, Circuit Judges.

Opinion by Judge Beezer

SUMMARY

Civil Litigation and Procedure/Jurisdiction/Standing/Health/Government Law/Food and Drug Administration/Administrative Law/Judicial Review

Affirming a district court judgment dismissing an action for lack of subject matter jurisdiction, the court of appeals held

that the Food and Drug Administration's classification of dietary supplement Co-enzime Q10 (CoQ10) as an unsafe food additive—because no FDA regulation prescribed the conditions under which it could be safely used—was not an issue ripe for judicial review.

Appellant Dietary Supplemental Coalition, Inc. (DSC), represents a coalition of dietary supplement manufacturers who challenged the Food and Drug Administration's (FDA) classification of a dietary supplement, Co-enzime Q10, as an unsafe food additive under the Food and Drug Act. The FDA had seized bottles of CoQ10 from member companies of DSC, ruling that it was an unsafe food additive because no FDA regulation prescribed the conditions under which it could be safely used. The FDA also issued regulatory letters concerning the dietary supplement to inform recipients that CoQ10 was an unapproved food additive whose continued marketing subjected its sellers to enforcement actions. DSC then filed an action in district court for declaratory relief, claiming that its products containing CoQ10 are "foods" and not "food additives," or are generally recognized as "safe" within the meaning of the Food and Drug Act. The district court granted the FDA's motion to dismiss, holding that the issues presented were not ripe for judicial review. DSC argued that despite the lack of a formal pronouncement on the general status of CoQ10, the FDA has made a decision regarding the product's classification sufficiently final for purposes of judicial review.

[1] In support of its argument that the FDA took final administrative action, DSC pointed to the FDA's seizure actions and the regulatory letters. [2] However, the court previously held that the issuance of regulatory letters is not final agency action. [3] Nevertheless, the court recognized a split in authority as to whether seizure actions are final agency action. [4] The court held, however, that specific product seizures do not amount to final agency action regarding any use of CoQ10. [5] The court noted that it has held that classifica-

tion of a product as "food" involves complex chemical and pharmacological considerations and a determination of technical and scientific questions. [6] Even if the FDA has been consistent in its approach to products containing CoQ10, seizures in themselves do not amount to a final agency position on all uses of the dietary supplement in question. The district court correctly held that the classification of "foods" and "food additives" is not a purely legal determination, and that the FDA did not waive its right to make that determination by taking a legal position in other separate actions. [7] In light of the court's rejection of DSC's finality argument, the court held that the district court correctly found that DSC failed to show sufficient hardship to require bypassing final agency action by the FDA. [8] The court acknowledged that the "futility" and "risk" arguments both stand on the assumption that the FDA made a final determination regarding the classification of CoQ10. However, because the court held otherwise, the most DSC showed was the pursuit of administrative remedies may be time consuming. That was insufficient for bypassing agency expertise and invoking the jurisdiction of the federal courts.

COUNSEL

I. Scott Bass, Piper & Marbury, New York, New York, for the plaintiffs-appellants.

Heidi A. Garland, United States Department of Justice, Civil Division, Washington, D.C., for the defendants-appellees.

OPINION

BEEZER, Circuit Judge:

We consider whether the Food and Drug Administration's classification of dietary supplement Co-enzyme Q10

("CoQ10") is an issue ripe for judicial review. The district court dismissed plaintiff's action for declaratory judgment on the grounds that 1) the issue raised was not purely legal; 2) the challenged action was not final; and 3) the plaintiffs had not exhausted their administrative remedies. Plaintiffs timely appeal. We affirm.

I

Plaintiffs-appellants are a coalition of dietary supplement manufacturers, known as the Dietary Supplement Coalition, and an Oregon dietary supplement distributor called the Health Haus, Inc. (referred to collectively as "DSC").

In 1989, the Food and Drug Administration ("FDA") initiated two proceedings to seize bottles of CoQ10 from Natural Organics, Inc., and Bio-Energy Nutrient, Inc., both member companies of DSC. The FDA stated that under the provisions of the Food and Drug Act, 21 U.S.C. § 321(s) (1988), CoQ10 was an unsafe food additive because no FDA regulation prescribed the conditions under which it could be safely used. The FDA also issued regulatory letters concerning CoQ10 informing recipients that CoQ10 was an unapproved food additive whose continued marketing subjected its sellers to enforcement actions.

DSC filed an action in district court for declaratory judgment. DSC claims that their products which contain CoQ10 are "foods" and not "food additives," or are "generally recognized as safe" within the meaning of the Food and Drug Act.

The district court granted the government's motion to dismiss, holding that the issues presented were not ripe for judicial review. DSC appeals, claiming that despite the lack of a formal pronouncement on the general status of CoQ10, the FDA has made a decision regarding the product's classification that is sufficiently final for the purpose of judicial review.

II

A ruling on subject matter jurisdiction is a question of law subject to *de novo* review. *Winter v. Calif. Medical Review, Inc.*, 900 F.2d 1322, 1324 (9th Cir. 1990). In determining ripeness issues, we evaluate "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 1325; *see also Abbott Lab. v. Gardner*, 387 U.S. 136, 149 (1967). The fitness element requires that the issue be primarily legal, need no further factual development, and involve a final agency action. *Winter*, 900 F.2d at 1325. To meet the hardship requirement, a party must show that withholding judicial review would result in direct and immediate hardship and would entail more than possible financial loss. *Id.*

DSC says that the FDA has made a final determination regarding the classification of CoQ10. We first consider the element of the ripeness inquiry requiring "final agency action."

In interpreting the finality requirement, we look to whether the agency action represents the final administrative work. This requirement insures judicial review will not interfere with the agency's decision-making process. *Winter*, 900 F.2d at 1324-25. The finality element must be interpreted in a "pragmatic" and "flexible" manner. *Abbott Lab.*, 387 U.S. at 149-50.

[1] In support of its argument that the FDA has taken final administrative action, DSC points to the seizure actions, the FDA regulatory letters, and the testimony of an FDA expert in a separate case. Because the expert testimony was not before the district court, it is not a part of the record on appeal. *See Kirshner v. Uniden Corp. of America*, 842 F.2d 1074, 1077 (9th Cir. 1988); Fed R. App. P. 10(a); Ninth Cir. R. 10-2.

[2] We have held that regulatory letters do not constitute final agency action. *See Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) (" '[T]he type of informal letter issued by the FDA . . . does not constitute the kind of formal or final agency action the Supreme Court had in mind . . ..' ") (quoting *IMS Ltd. v. Califano*, 453 F. Supp. 157, 160 (C.D. Cal. 1977)); *see also Estee Lauder, Inc. v. United States Food and Drug Admin.*, 727 F. Supp. 1, 5 (D.D.C. 1989) (FDA regulatory letter was "informal and advisory" and did not constitute final agency action).

DSC seeks to analogize this case to *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986). In *Ciba-Geigy*, the EPA sent a letter detailing the agency's position regarding certain procedures required for labeling changes. The district court held that this letter was sufficiently final and ripe for review even before EPA enforcement of its position. *Id.* at 434. However, *Ciba-Geigy* involved a dispute over procedure and not product classification. Because classification requires agency expertise, *Ciba-Geigy* is inapposite to the case at hand.

[3] There is a split in authority as to whether seizure actions constitute final agency action.[1] The district court distinguished the cases in favor of DSC's position on the grounds that, in each case, the FDA had come to a definitive position. DSC disagrees, contending that in neither case had the FDA made a final decision regarding the product's classification.

---

[1]*Compare Premo Pharmaceutical Lab., Inc. v. United States*, 629 F.2d 795, 799 (2d Cir. 1980) (holding that referring the issue to FDA would be "wasteful and duplicative" in case where FDA had filed seizure actions after rejecting Premo's attempt to file drug with agency); *and Natick Paperboard Corp. v. Weinberger*, 498 F.2d 125, 129 (1st Cir. 1974) (holding that district court had jurisdiction to grant declaratory relief where the FDA had made announcement that it would seize "certain food-packaging materials containing more than 10 ppm of PCB's"), *with Schering Corp. v. Heckler*, 779 F.2d 683, 686 n.18 (D.C. Cir. 1985) (holding FDA seizure action did not constitute final agency action).

While DSC correctly points out that the FDA had not come to a final conclusion as to product classification in *Premo* and *Natick*, in both cases the agency had taken an explicit position as to the product at issue. In *Premo*, the agency had considered and refused to approve an application from plaintiff Premo to market the drug at issue. *Premo*, 629 F.2d at 799. In *Natick*, the agency had already published a regulation banning Natick's food packaging material as violative of the Act. *Natick*, 498 F.2d at 126. In the present case, the FDA has made no statement regarding CoQ10 in general; only its use in certain products has been challenged.

[4] The only "agency statement" DSC can point to regarding the general use of CoQ10 is the previously rejected expert testimony. Even under *Abbott*'s "pragmatic and flexible" approach to determining finality, specific product seizures do not amount to final agency action regarding *any* use of CoQ10.[2]

III

[5] We have held that classification of a product as "food" involves " 'complex chemical and pharmacological considerations,' and 'determination of technical and scientific questions.' " *Biotics*, 710 F.2d at 1377 (citations omitted). In such cases, a district court should decline to review anything less than a final administrative determination on the classification of the product. *Id.* at 1377. *See also Estee Lauder*, 727

[2]The cases are also distinguishable on the ground that, unlike the plaintiffs in *Premo* and *Natick*, DSC has made no attempt to use available administrative remedies. In *Natick*, the plaintiffs filed an objection to the FDA regulation insofar as it affected their product. *Natick*, 498 F.2d at 126. The Commissioner of Food and Drugs then announced that, until he reached a final decision on the objections, he would enforce *de facto* compliance with the new regulation by recommending seizure of any product that violated the challenged regulation. *Id.* In *Premo*, plaintiffs initially filed a new drug application with the FDA. *Premo*, 629 F.2d at 799. The FDA found the data submitted with the application insufficient and requested further evidence. *Id.*

F. Supp. at 4-5 (the decision to classify a product as a "food additive" is a fact-based determination and judicial review prior to final agency action would "deny the [FDA] the full opportunity to apply its expertise and to correct errors or modify positions in the course of a proceeding").

DSC seeks to distinguish *Biotics* on the grounds that the FDA has completed its factual investigations regarding CoQ10. In essence, DSC claims that there is no need to defer to agency expertise in making a factual determination when the agency has already made up its mind. To support its argument, DSC cites the FDA seizures.[3]

[6] Even if the FDA has been consistent in its approach to products containing CoQ10, seizures in themselves do not amount to a final agency position on all uses of CoQ10. As DSC points out, FDA's motions for summary judgment in other cases involving CoQ10 assume that the classification decision in those cases could be reviewed as a matter of law. However, the FDA is not bound by a previous position taken in a different case with different facts. The district court correctly held that the classification of "foods" and "food additives" is not a purely legal determination; the FDA has not waived its right to make that determination by taking a legal position in separate actions.

IV

The final element of the ripeness inquiry is hardship. A party must show that withholding judicial review would result in direct and immediate hardship and would entail more than possible financial loss. *Winter*, 900 F.2d at 1325. The district court found DSC's risk of additional seizures and injunction actions "too speculative to warrant judicial intervention."

[3]DSC also attempts to use the FDA expert testimony from a separate case in support of its argument that the agency has come to a conclusion about the status of CoQ10. As previously discussed, this testimony is not part of the record on appeal.

[7] DSC claims the district court erred in failing to distinguish between the potential risks of tentative FDA policy statements and the very real liabilities imposed by a final, announced enforcement position and actual seizures. Again, DSC's position assumes that the FDA has made a final determination as to the general status of CoQ10. In light of our rejection of DSC's finality argument, we hold the district court correctly found that DSC failed to show sufficient hardship to require bypassing final agency action by the FDA.

V

Although we have indicated that the traditional exhaustion requirement applies to one seeking judicial review of FDA status determinations, the requirement is not absolute. *See Biotics*, 710 F.2d at 1378. Exhaustion will not be required if administrative remedies are "inadequate or not efficacious" or where pursuit of administrative remedies would be a "futile gesture." *Id.*; *Winter*, 900 F.2d at 1326.

DSC does not dispute the availability of administrative remedies. Rather, it claims that exhaustion principles do not apply when the issue involved is a legal one. As previously discussed, classifications of food and food additives are fact-based determinations.

DSC also claims that pursuing administrative remedies is futile when the agency has already made a final determination. Contending that remedies such as a citizen petition can take over a year to be resolved, DSC claims this wrongly subjects its members to the risk of future seizures and possible criminal fines.

[8] The "futility" and "risk" arguments both stand on the assumption that the FDA has made a final determination regarding the classification of CoQ10. Because we hold otherwise, the most DSC has shown is that the pursuit of administrative remedies may be time consuming. This is insufficient

justification for bypassing agency expertise and invoking the jurisdiction of the federal courts. The district court's dismissal for want of subject matter jurisdiction is

AFFIRMED.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

DIETARY SUPPLEMENT COALITION, INC., et al.,	)	
Plaintiffs,	)	Civil No. 91-126-RE
vs.	)	
LOUIS W. SULLIVAN, M.D., SECRETARY OF HEALTH AND HUMAN SERVICES, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, and FOOD AND DRUG ADMINISTRATION,	)	OPINION
Defendants.	)	

Richard Botteri
Weiss, Jensen, Ellis & Botteri
2300 US Bancorp Tower
111 S.W. Fifth Avenue
Portland, Oregon 97204

I. Scott Bass
Robert A. Sellers, Jr.
Bass & Ullman
747 Third Avenue
New York, New York 10017
Attorneys for plaintiffs

Charles H. Turner
United States Attorney
District of Oregon
Judith D. Kobbervig
Assistant United States Attorney
888 S.W. Fifth Avenue, Suite 1000
Portland, Oregon 97204

Darya Geetter, Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Attorneys for defendants

REDDEN, Judge:

BACKGROUND

Plaintiffs filed this action for a declaratory judgment that their products which contain Co-enzyme Q10 (CoQ10) are "foods" and not "food additives," or, are "generally recognized as safe" within the meaning of the Food and Drug Act, 21 U.S.C. § 301 (the Act). Such a determination would exempt plaintiffs' products from premarket review by the Food and Drug Administration (FDA). Defendants filed a motion to dismiss alleging that since the FDA has not made a final determination regarding plaintiffs' CoQ10 products, there is no controversy for the court to decide, and

plaintiffs' claim is not ripe for review. Further, defendants allege that plaintiffs have failed to exhaust their administrative remedies.

Plaintiff Dietary Supplement Coalition, Inc., is an incorporated trade association of "food and dietary supplement" manufacturers, whose purpose is to redress the FDA's alleged "improper attempts to eliminate safe dietary supplements from the market." Plaintiff Health Haus is a corporation that distributes products including those containing the ingredient CoQ10. Some of the member companies of plaintiff Dietary Supplement Coalition have also engaged in distributing CoQ10.

In 1989, the FDA initiated two proceedings to seize bottles of CoQ10 from Natural Organics, Inc., and Bio-

Energy Nutrient, Inc.; member companies of plaintiff Dietary Supplement Coalition. The FDA stated that under the provisions of the Act, CoQ10 is an unsafe food additive because there is no FDA regulation prescribing the conditions under which it may be safely used. The FDA also issued regulatory letters concerning CoQ10 informing recipients that CoQ10 is an unapproved food additive whose continued marketing subjects it and its sellers to enforcement action.

I grant defendants' motion to dismiss and dismiss this action.

STANDARDS

Under Fed. R. Civ. P. 12(b)(6), dismissal for failure to state a claim is proper only when it appears to a certainty that the plaintiffs can prove no set of facts in support of their claim

that would entitle them to relief. Litchfield v. Spielberg, 736 F.2d 1352, 1357 (9th Cir. 1984), cert. denied, 470 U.S. 1052 (1985). For the purpose of a motion to dismiss, the complaint is liberally construed in favor of the plaintiffs, and its allegations are taken as true. Rosen v. Walters, 719 F.2d 1422, 1424 (9th Cir. 1983).

DISCUSSION

1. Ripeness

In deciding whether an issue is ripe for review, the courts must evaluate "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott Laboratories v. Gardner, 387 U.S. 136, 149 (1967).

A. ISSUES FIT FOR JUDICIAL RESOLUTION

(1) Food vs. Food Additive

A claim is fit for decision if the issues raised are purely legal and do not require further factual development, and the challenged action is final. Abbott Laboratories, 387 U.S. at 149. I find that plaintiffs' claims do not raise purely legal questions. Plaintiffs' allege that CoQ10 is "normally sold in a capsule form without other nutrients," and that it "has enormous benefits for health by providing a rich source of nutrients . . . ." Those allegations do not give this court a legal basis to determine that CoQ10 is a "food" and not a "food additive" within

the meaning of the Act. The Ninth Circuit held:

> classification of a products as a . . . food involves the same complex chemical and pharmacological considerations, and determination of technical and scientific questions, that led the Supreme Court to conclude that new drug decisions are best left to agency expertise. We therefore conclude that it is appropriate for a district court to decline reviewing anything less than a final administrative determination on the classification of a product . . . .

Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1377 (9th Cir. 1983). I also rely on Estee Lauder, Inc. v. FDA, 727 F. Supp. 1, 4-5 (D.D.C. 1989), where plaintiff sought a legal determination that its cosmetic products were not misbranded drugs under the Act. The court granted defendant's motion to dismiss holding:

> ripeness and finality considerations prevent [this court] from declaring that the FDA's position is .

> unreasonable, arbitrary, and capricious. First, the issue of whether Lauder's skin creams are improperly making drug-like claims is not purely a legal question . . . . This court would also have to make a fact-based determination as to the "intended use" of each of the Lauder products. Such a factual review would deny the [FDA] the full opportunity to apply its expertise and to correct errors or modify positions in the course of a proceeding . . . . These considerations weigh strongly in favor of dismissal when the court is asked to rule on a factual question, particularly within the agency's bailiwick as opposed to a purely legal question within the primary competence of the courts.

Id. at 4 (citations omitted).

Therefore, determining whether plaintiffs' CoQ10 products are "foods," rather than "food additives," is not a purely legal question, and therefore is not an issue ripe for this court.

Plaintiffs respond that the determination is purely a legal one and "turns entirely on a reading of the

legislative history behind the Act as well as an analysis of the relevant case law and a determination of whether a CoQ10 capsule can truthfully be classified as a substance used to flavor, stabilize or sterilize food."
Plaintiffs' Memo in Opposition, p.13.

Plaintiffs contend that Estee Lauder can be distinguished because the court there found that judicial review would have interrupted an "ongoing" agency decision-making process that involved merely a "tentative" agency position. Id. at 4-5. However, the court also held that the issue of whether Lauder's skin creams are improperly making drug-like claims was not a purely legal question. The court found it would be necessary to engage in an extensive fact-based determination in order to resolve the

dispute. "Such a factual review would deny the Administration the full opportunity to apply its expertise and to correct errors or modify positions in the course of a proceeding. Id. at 4. The court held that these considerations "weigh strongly in favor of dismissal when the court is asked to rule on a factual question particularly within the agency's bailiwick as opposed to a purely legal question within the primary competence of the courts." Id.

Plaintiffs here also argue that the Biotics case "rested its entire decision" on the finding that the agency was not committed to an enforcement action. Plaintiffs' Memo in Opposition, p.15. However, Biotics did not address the existence of any factual dispute regarding the classification of a product

by the FDA. Biotics focused only on whether there had been final agency action, and after concluding there had not been, did not reach the issue of whether the FDA had properly classified the product.

Here, defendants contend that a factual issue exists as to the proper classification of the food or food additive that should not be resolved by the courts. I agree that a factual issue does exist as to whether plaintiffs' product is properly classified as a food or food additive and that issue is properly resolved by the agency, not the courts. As in Estee Lauder, this court would be put in the position of having to make a factual determination in an area where the FDA holds the expertise and the courts do not. In the cases relied on by

plaintiffs, the courts state that the parties agree that there is no factual dispute about whether the proposed classification or rule is purely a legal question. Here, there is clearly a dispute by defendants, who argue that the classification is not a legal question, but one of factual determination.

(2) Issue Ripe for Judicial Review

Defendants also argue that this issue is not fit for judicial decision because there has been no final agency action. "In interpreting the finality requirement, a court looks to whether the agency action represents the final administrative work to insure that judicial review will not interfere with the agency's decision-making process." Winter v. Cal. Medical Review, 900 F.2d 1322, 1324-25 (9th Cir. 1990).

Defendants assert that the FDA's actions to enforce the Act, the issuance of regulatory letters and the two seizures of CoQ10, do not constitute final agency action. See Biotics, 710 F.2d at 1377 ("the type of informal letter issued by the FDA . . . does not constitute the kind of formal or final agency action the Supreme Court had in mind . . . ."); and Estee Lauder, 727 F. Supp. at 4-5 ("by its very nature the [FDA regulatory letter was] informal and advisory," and did not constitute final agency action).

Defendants assert that the seizures also do not represent final agency action. Schering v. Heckler, 779 F.2d 683 (D.C. Cir. 1985). In Schering, the FDA instituted a seizure action against a new animal drug (for chicks), secured a default judgment, and destroyed a quantity

of the new drug. The court held that these actions "do not constitute final agency action ...." Id. at 686 n.18.

Plaintiffs argue that seizure by the FDA does constitute final agency action making the issue ripe for review by a court. Plaintiffs rely on Ciba-Geigy Corp. v. U.S. Environmental Protection Agency, 801 F.2d 430, 436 (D.C. Cir. 1986). Ciba-Geigy held that a letter sent by the EPA which detailed the agency's position regarding the procedures required for labeling changes on pesticide products was sufficiently final and ripe for review even before enforcement of that agency position. Id. at 434. Further, "courts confronted with close questions of ripeness are appropriately guided by the presumption of reviewability, especially when the affected person is confronted

with the dilemma of choosing between disadvantageous compliance or risking imposition of serious penalties." Id.

In reaching its decision, Ciba-Geigy relied on Abbott Laboratories' instruction to apply the finality requirement in a "flexible" and "pragmatic" way. Abbott Laboratories, 387 U.S. at 149-50. In particular, a court looks to whether the agency's position is "definitive" and whether it has a "direct and immediate ... effect on the day-to-day business" of the parties challenging the action. FTC v. Standard Oil Co., 449 U.S. 232, 239 (1980). Ciba-Geigy held:

> these indicia of finality are ordinarily controlling because they are highly probative of whether the agency's position is merely tentative, or on the other hand, whether the agency views its deliberative process as sufficiently final to demand compliance with its announced position. The interest in postponing review is powerful when

> the agency position is tentative. ... Once the agency publicly articulates an unequivocal position, however, and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review.

Id. at 436 (emphasis added).

However, the distinguishing factor between the case at bar, and Ciba-Geigy, is that the latter case presented the "narrow legal question" as to what procedures EPA was obliged to follow before requiring a labeling change. The court noted that that legal issue "is entirely independent of and separable from the largely factual question whether [the chemical at issue] poses substantial danger of groundwater contamination." Id. at 435. Contrary to our case, the plaintiffs' complaint in Ciba-Geigy did not challenge the merits of EPA's labeling

requirements or the sufficiency of EPA's case for misbranding. Id.

Defendants admit that there seems to be a split of authority on whether FDA seizures constitute final agency action. However, defendants distinguish the cases where a the courts approved a seizure as final agency action because the FDA had already considered and refused to approve an application from plaintiff Premo to market the drug at issue. See Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 799 (2d Cir. 1980). When the FDA threatened the seizure of plaintiff Natick's food packaging material, the agency had already published a regulation banning that food packaging material as violative of the FDC Act. See Natick Paperboard Corp. v. Weinberger, 498 F.2d 125, 126 (1st Cir.

1974). In both of these cases, plaintiffs had already used their administrative remedies.

Defendants argue both the refusal to approve Premo's drug, and the issuance of the regulation prohibiting Natick's food packaging, were final FDA actions reviewable in the courts of appeals. The FDA's position on the products at issue in Premo and Natick Paperboard was definitive at the time the seizures of those products were filed. Therefore, the seizure of the products in the case at bar were more like the seizures in Schereing, where the seizures were neither based upon, nor do they establish, final agency action.

Defendants also argue that a claimant can contest a seizure action under the Act at 21 U.S.C. § 334. Further, Natural Organics, Inc. is currently litigating the

seizure action initiated against its CoQ10 products in a New York District Court. Defendants argue that that forum is the proper one within which to raise claims regarding the status of CoQ10. In the seizure of CoQ10 from Bio-Energy Nutrient, Inc., that company permitted the product to be condemned by default. [Cv. No. 89-M1095 (D. Colo. Aug. 28, 1989)].

2. Hardship to the Parties of Withholding Judicial Review

Defendants contend that plaintiffs have not shown that they would suffer hardship "sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage." Abbott Laboratories, 387 U.S. at 152. The hardship must entail more than "possible financial loss." Cal. Dept. of

Educ. v. Bennett, 833 F.2d 827, 833-34 (9th Cir. 1987).

Defendants contend that the hardship plaintiffs allege is speculative and hypothetical. See Complaint, para. 20 ("there may be additional seizures and/or injunction actions against members of the DSC or Health Haus should these companies continue to sell CoQ10 in interstate commerce"). Estee Lauder stated, "because [plaintiffs are] seeking a pre-enforcement review of a projected agency position, the claimed hardship is no greater than any company confronted by an interpretation of a law it dislikes." Id., 727 F. Supp. at 5.

Plaintiffs contend that they are subject to direct and immediate hardship. Either they must comply with FDA's "unsafe food additive" interpretation with respect

to their CoQ10 products; or follow their present course and "risk additional seizure actions and/or criminal sanctions." Plaintiff's Memo in Opposition, p.24.

Based on the allegations of harm in plaintiffs' complaint ("there may be additional seizures and/or injunction actions against members of the DSC or Health Haus should these companies continue to sell CoQ10 in interstate commerce"), I find that it is to speculative to warrant judicial intervention. As Estee Lauder noted, "because [plaintiffs are] seeking a pre-enforcement review of a projected agency position, the claimed hardship is no greater than any company confronted by an interpretation of a law it dislikes." Id. at 5.

3. Failure to Exhaust Administrative Remedies

The primary purpose of the exhaustion requirement "is to allow an administrative agency to perform functions within its special competence - to make a factual record, to apply its expertise, and to correct its own errors so as to moot judicial controversies." Sierra Club v. Union Oil Co. of California, 813 F.2d 1480, 1486 (9th Cir. 1987).

Defendants contend that plaintiffs can exhaust their administrative remedies by filing a "citizen petition" asking the FDA for formal determination of CoQ10's status as a food or food additive. 21 C.F.R. § 10.25(a) (1990). The plaintiffs do not deny this. The Commissioner's decision on such a petition is generally due within 180 days, 120 C.F.R. § 10.30(e)(2). The decision is reviewable

in federal court as final agency action, 21 C.F.R. § 10.45(d), after an appropriate administrative record is developed, 21 C.F.R. § 10.30(i).

Additionally, plaintiffs can petition the FDA to conduct a proceeding to determine that their products are "generally recognized as safe" (GRAS). 21 C.F.R. §§ 170.35, 170.38. Plaintiffs also have failed to avail themselves of the FDA's internal process for obtaining review of the position expressed in a regulatory letter. 21 C.F.R. § 10.75. Defendants claim that plaintiffs have neither availed themselves of these administrative remedies nor have they alleged, or established, that it would be futile to address their concerns to the FDA. See Biotics, 710 F.2d at 1378 ("nothing in the record to indicate that a

citizen's petition to the Commissioner would [be] ineffective or futile"). I agree.

CONCLUSION

Defendant's motion to dismiss is granted. I find that the issues presented are not fit for judicial resolution because: (1) the issues raised are not purely legal and require further factual development; (2) the challenged action is not final; and (3) plaintiffs have not exhausted their administrative remedies. Further, plaintiff's Motion to Extend the Discovery Schedule is denied as moot.

Dated this 8 day of July, 1991.

/s/
James A. Redden
United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing CIVIL APPEALS DOCKETING STATEMENT on:

Judith D. Kobbervig
Assistant United States Attorney
888 S. W. Fifth Avenue, Suite 1000
Portland, OR 97204

Gerald Kell
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

by overnight mail, addressed to the above attorneys, contained in an envelope with postage prepaid, and deposited in the post office at Portland, Oregon this 3rd day of October, 1991.

/s/
Christopher T. Carson, OSB 84450
Of Attorneys for Plaintiffs

In the

United States Court of Appeals

for the Seventh Circuit

No. 92-1172
UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

TWO PLASTIC DRUMS, MORE OR LESS OF AN ARTICLE OF FOOD, LABELED IN PART: VIPONTE LTD. BLACK CURRANT OIL BATCH NO. BOOSF 039, etc., and TRACO LABS, INCORPORATED,

Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Danville Division.
No. 88 C 2398-Harold A. Baker, Judge.

ARGUED OCTOBER 21, 1992 - DECIDED JANUARY 27, 1993

Before CUDAHY and EASTERBROOK, Circuit Judges, and WILL, Senior District Judge.*

CUDAHY, Circuit Judge. The Food and Drug Administration ("FDA") brings this *in rem* seizure action under the Food, Drug and Cosmetic Act, 21 U.S.C. §§301 *et seq.* ("Act"), seeking to condemn and destroy two drums of black currant oil as adulterated under 21 U.S.C. §342(a)(2)(C) for being a food additive not recognized as safe. The district court granted summary judgment against the FDA, and the government appeals. We affirm.

---

* The Honorable Hubert L. Will, Senior District Judge for the Northern District of Illinois, is sitting by designation.

I.

Black currant oil ("BCO") is extracted from the seeds of the black currant berry and is marketed as a dietary supplement for its unique fatty-acid structures. The FDA argues that BCO is a food additive not generally recognized as safe ("GRAS") and seeks to seize and condemn two drums of BCO pursuant to sections 334 and 342 of the Act. A food is adulterated and subject to seizure under section 334 "if it is, or it bears or contains, any food additive which [the Secretary has not recognized as safe pursuant to section 348]." 21 U.S.C. § 342(a)(2)(C). The determination of whether a substance is a food additive is critical in establishing the safety of the substance because, if the substance is deemed a food additive, it is presumed to be unsafe, and the processor has the burden of showing that the substance is GRAS. On the other hand, if a substance is not a food additive, but food in the generic sense,[1] then the substance is presumed safe and the FDA has the burden of showing that the substance is injurious to health. United States v. An Article of

---

[1]Because food additives can be thought of as a subset of food in the broadest sense, see Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 337 (7th Cir. 1983), reference to food in the generic sense refers to articles of food not considered food additives.

Food ..:. Food Science Labs., 678 F.2d 735, 739 (7th Cir. 1982).

The Act defines "food additive" as

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use...

21 U.S.C. §321(s). The FDA contends that BCO is a food additive because it is a "component" of food when it is combined with the gelatin and glycerin used to market the BCO in capsules. The gelatin and glycerin encase the BCO to prevent it from becoming rancid. The FDA concedes that if the BCO alone was marketed in bottles for teaspoon consumption, it would not be a food additive, and the FDA would

bear the burden of proving that BCO is injurious to health. But the combination of BCO with glycerin and gelatin, the FDA maintains, creates a food consisting of three components, and thus, three food additives.[2] In this instance, therefore, the FDA would require the processor to prove that the substance is safe - something that Traco Labs, the claimant of the two drums of BCO, has not done.

The district court granted summary judgment against the FDA, holding that the FDA's definition of food additive "would obscure any distinction between 'foods' under §321(f) and 'food additives' under §321(s)" contrary to the intent of Congress. United States v. Two Plastic Drums, More or Less of an Article of Food...(Traco Labs), 791 F. Supp. 751, 754-55 (C.D. Ill. 1991); see also 761 F. Supp. 70, 74 (C.D. Ill. 1991) (order denying FDA's motion for summary judgment).

II.

We review the grant of summary judgment de novo. Overton v. Reilly, 977 F.2d 1190, 1191 (7th Cir. 1992). Summary judgment is appropriate when there is no genuine issue of any material fact and the

---

[2]Because gelatin and glycerin are GRAS, they are not formally considered "food additives" under the statute.

moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). The sole issue presented in this action is whether BCO, when combined with glycerin and gelatin, is a food additive pursuant to section 321(s). In determining what is a food additive, we look first to the language of the statute itself, Consumer Product Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980), and if the language of the statute is plain, then it is conclusive absent contrary legislative intent. United States v. Ron Pair Enters., Inc., 489 U.S. 235 (1989). Section 321(s) defines a food additive as "any substance the intended use of which results... in its becoming a component or otherwise affecting the characteristics of any food..." This language is very broad, and thus, the general rule is that a component of an article of food is a food additive, even if the component in question is the "principal component," i.e. the ingredient sought when purchasing the food. FoodScience, 678 F.2d at 738. Moreover, even substances ordinarily considered "food" in common usage may become food additives in some circumstances. National Nutritional Foods Ass'n v. Kennedy, 572 F.2d 377, 391 (2d Cir. 1978) (vitamins and minerals may be food additives when added to food). In addition, this court has held that DDT found naturally in fish is a food additive under the broad language of the Act. United States v. Ewig Bros. Co., 502 F.2d 715, 721-24 (7th Cir. 1974) (Stevens, J.), cert. denied sub nom., Vita Foods Prods.

of Illinois, Inc. v. United States, 420 U.S. 945 (1975).

The FDA argues that the statutory language clearly indicates that any and every component of an article of food is a food additive. Although we are mindful of the deference due to FDA in construing the statute is administers, Young v. Community Nutrition Inst., 476 U.S. 974, 981 (1986) Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837, 843-44 (1984); United States v. 25 Cases, More or Less, of An Article of Device, 942 F.2d 1179, 1182 (7th Cir. 1991), deference here is unwarranted since its interpretation is contrary to the language and intent of the Act. Demarest v. Manspeaker, 498 U.S. 184 (1991) (administrative interpretation of statute contrary to plain language is not entitled to deference). As an initial matter, we question whether BCO can even be considered a "component" under the Act. The term "component", commonly understood and defined as a "constituent part" or "ingredient", Webster's Third New International Dictionary 466 (1976), loses its meaning when applied to foods used in conjunction with inactive ingredients, as this case amply evidences. Here, the dietary supplement (the food) is nothing but BCO combined with glycerin and gelatin - two inactive substances used for marketing the BCO in capsule form. The gelatin and glycerin do not interact with or change the character of the BCO, but merely act as a container comparable to a bottle containing liquids marketed for teaspoon consumption. The BCO in question is the dietary supplement and the dietary

supplement is the BCO. Therefore, to hold that BCO is a component of the dietary supplement would be to find that BCO is a component of itself. Such an interpretation would defy logic and common sense.

But even assuming that a single active "ingredient" of food can be considered a component of the food, the statutory language does not indicate that every component of food is necessarily a food additive. The Act defines "food additive" as a substance "becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. §321(s) (emphasis added). The FDA interpretation of this provision implies that the language "or otherwise" is used disjunctively in such a way that a substance is a food additive if (1) is a component of any food, or (2) affects the characteristics of a food. We think that this interpretation, however, distorts the plain meaning of the provision. The phrase "or otherwise", as employed here, is not used to express two alternative definitions of a food additive. Rather, it is used in a way to clarify or elaborate, such that "otherwise" is correctly read as "similarly". This view comports with established principles of statutory construction holding that courts should rein in broad and general statutory language when such language is immediately coupled with more limiting language or a specific enumeration. 2A Norman J. Singer, Sutherland on Statutory Construction §§47.16, 47.17 (5th ed. 1992) (reviewing doctrines of noscitur a sociis

(coupling of words denotes an intention that they be understood in same general sense) and ejusdem generis (general words coupled with statutory enumeration are construed only to embrace objects similar in nature)); see also Toilet Goods Ass'n v. Gardner, 278 F. Supp. 786, 790 (S.D.N.Y. 1968) (employing doctrine of ejusdem generis to limit expansive application of color additive provision), aff'd in relevant part, rev'd in part sub nom., Toilet Goods Ass'n v. Finch, 419 F.2d 21 (2d Cir. 1969). The phrase "becoming a component" in section 321(s) is immediately followed by more descriptive language relating to the substance's effect on food. Moreover, the examples of food additives then enumerated in the Act describe the substances by their function or by their effect on food. 21 U.S.C. §321(s) (listing as examples of food additives "any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use"); cf. 104 Cong. Rec. 17,417 (remarks of Rep. Williams) ("substances which are used to improve the characteristics of our food are illustrative of the kinds of things this legislation deals with."); Harry A. Toulmin, Jr., Treatise on the Law of Foods, Drugs and Cosmetics §§22.5-11.10 (2d. ed. 1963) (grouping food additives according to function). Therefore, simply becoming a "component" of food does not, in and of itself, satisfy the definition of a food additive. To be a food additive, a substance must not only be

added to food, but it must also have the purpose or effect of altering a food's characteristics.[3]

When two or more active ingredients comprise a food, each component is arguably different from the food in such a way that the addition of each has affected the characteristics of the other components and of the food. Thus, courts faced with foods involving two or more active components have held that each component is a food additive. See United States v. 45/194 Kg. Drums of Pure Vegetable Oil, 961 F.2d 808, 812 & n.3 (9th Cir.) (Evening Primrose Oil ("EPO") held food additive when encapsulated with Vitamin E, since "EPO is not a single ingredient" - distinguishing the case of BCO encapsulated alone), cert. denied sub nom., Efamol, Ltd., v. United States, 113 S. Ct. 375 (1992); FoodScience, 678 F.2d at 738 (principal ingredient of food a food additive if combined with another active ingredient); United States v. 41 Cases, More or Less, etc., 420 f.2d 1126, 1130 (5th Cir. 1970) (medicated poultry feed found adulterated as containing two-three active ingredients held to be food

---

[3]Although certainly not controlling, our interpretation also reflects the common understanding of an additive, defined by Webster as "a substance added to another in relatively small amounts to impart or improve desirable properties or suppress undesirable properties." Webster's, supra, at 24.

additives); United States v. 42/30 Tablet Bottles, 779 F. Supp. 253 (E.D.N.Y. 1991) (two active non-chemical ingredients of dietary supplement held food additives); United States v. 21 Approximately 180 Kg. Bulk Metal Drums, 761 F. Supp. 180 (D. Me. 1991) (BCO held food additive when encapsulated with fish oil and various vitamins and minerals). But when there is only one active component, as is the case here, that single component does not affect the characteristics of the food in question - rather, it constitutes the food. Thus, even if we were to find that BCO was a component of the BCO dietary supplement capsules, the language of the Act indicates that it is not a food additive because, as the single active ingredient, it does not affect the characteristics of any food.

This interpretation is buttressed by the structure and history of the Act. The language of the Act must be read in the light of the statute as a whole: its design, objectives and policy. Crandon v. United States, 494 U.S. 152 (1990); Illinois EPA v. United States EPA, 947 F.2d 283 (7th Cir. 1991). Upon reviewing the structure and evolution of food regulation under the Act, it is clear that Congress intended to distinguish food additives from food in the generic sense. The original Food and Drug Act of 1906 required the government to prove that foods containing poisonous substances were unsafe. The addition of deleterious substances alone would not necessitate a finding of adulteration. United States v. Lexington Mill & Elevator Co., 232 U.S.

399 (1914). The Act was revamped in 1938, adopting a "per se" approach: It prohibited the use of poisonous or deleterious substances unless the industry proved that the addition of the substances was safe. See Ewig Bros., 502 F.2d at 720; Toulmin, supra §§ 1.5, 2.1, 2.3. The 1938 Act itself proved inefficient and Congress took steps to amend the Act in the early 1950's. Congress perceived essentially two flaws in the regulatory scheme. First, the government had the burden of first proving that a food additive is poisonous or deleterious before it could prevent the industry from using it. This required substantial time, during which the industry could market the potentially injurious additives to the consuming public. The second problem was that the law prevented processors from using certain additives in harmless amounts that, if used, would increase and improve the food supply. S. Rep. No. 2422, 85th Cong., 2d Sess. (1958), reprinted in 1958 U.S.C.C.A.N. 5300, 5301; Toulmin, supra, § 22.3.

After six years of extensive hearings, Congress passed the Food Additives Amendment Act of 1958. The thrust of the amendments was to put upon processors rather than the government the burden of proving that a newly discovered substance added to food is safe if used within specified quantities. The Act, however, did not require processors to prove that all of their marketed food was safe, although Congress would have been free to enact such a requirement. Rather, the burden imposed upon processors applied

only to food additives, and the government retained - as was the case prior to the 1958 amendment - the burden of proving that a given food was unsafe.

Consequently, the Act distinguishes between food additives and food in the generic sense, and this distinction is critical in allocating the burden of proof. The FDA's food additive definition is so broad, however, that it would blur this distinction. It would classify every component of food - even single active ingredients - as food additives. Thus, it would seem, even the addition of water to food would make the food a food additive. the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances. To be sure, the paramount objective of the Act is to protect the public health. But "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." 62 Cases of Jam v. United States, 340 U.S. 593, 600 (1951).

The FDA's interpretation would also arbitrarily classify a substance as either food or food additive by how it is marketed rather than by the nature and use of the substance itself. The FDA concedes that BCO marketed in bottles instead of in capsule form is not a food additive, and that it would in that event have the

burden of proving that the BCO is harmful or deleterious. Yet there is no difference between the BCO bottled for teaspoon consumption and the encapsuled BCO but for the way it is marketed. How a product is marketed is not a rational way of determining whether a substance is a food additive and which party - the FDA or the processor - bears the burden of proving its effect, if any, on the consuming public.

Therefore, although a component of food is generally a food additive, when the "component" is the single active ingredient and thus in all material respects is identical to the food of which it is supposedly a component but for certain inactive additions, such as the gelatin and glycerin used for encapsulation here, the substance in question is not a food additive. Our holding today is not inconsistent with FoodScience, the case on which the FDA relies. In that case, this Court held that the substance N, N-dimethylglycine hydrochloride ("DMG") - the lesser by weight and volume of two active components of the tablet Aangamik 15 - was a food additive even though DMG was the "principal ingredient" of the tablets. 678 F.2d at 738. The DMG, even though it was the reason consumers would purchase Aangamik 15, comprised only 4 percent of the tablets' weight, and was mixed with another active ingredient (calcium gluconate) to form Aangamik 15. We did not reach the question presented here where the substance at issue is the single active ingredient of a marketed product.

The district court in FoodScience enjoined the use of DMG "except when offered as a single ingredient for food use." But because the government did not cross-appeal from the exception, we refused to consider that question. Id. at 737 & n.2. Indeed, if the majority opinion had held what the FDA alleges it held, the concurrence in that case, on which the district court below relied, would have been a dissent. The concurrence states:\

> I believe ... as did the district court, that this would be a far different case if DMG were being marketed as a single food ingredient. In that case, the FDA would not be entitled to rely on the "food additive" presumption to condemn plaintiff's product but would instead be obligated to shoulder its normal burden of proving, by a preponderance of the evidence, that DMG was an "adulterated food" ....

Id. at 741 (Cudahy, J., concurring) (footnote omitted). In short, this case is different from FoodScience and other cases in which the substance in question was mixed with other active ingredients to form an arguably distinct article of food. See 45/194 Kg. Drums of Pure Vegetable Oil, 961 F.2d at 812 & n.3; 41 Cases, More or Less, 420 F.2d at 1130; 42/30 Tablet Bottles, 779 F. Supp. at 253; 21 Approximately 180 Kg. Bulk Metal Drums, 761 F. Supp. at 180. In fact, the rule enunciated today is supported by every court that has addressed the precise question involved here. See United States

v. 29 Cartons of an Article of Food ... Oakmont Inv. Co., 792 F. Supp. 139 (D. Mass. 1992) (encapsuled BCO not food additive); United States v. Vitality Systems, Inc., Food Drug Cosm L. Rep. ¶38,251 (D. Or. August 6, 1991) (holding that methylsulfonylmethane ("MSM") marketed in pure form not food additive but MSM held food additive in multi-ingredient products containing other nutrients such as Vitamin C); United States v. Undetermined Quantities of Articles of Food ... Blue-Green Algae, No. 83-1180-FR, 1984 WL 1981 (D. Or. November 8, 1984) (encapsuled Aphanizomenon flos-aquae (blue-green algae) not food additive because it was not intended to affect the characteristics of another food or become component of another food); United States v. An Article of Food ... L-Tryptophan, No. 77-687 (D.N.J. January 23, 1979) (L-Tryptophan tablets not food additive).

III.

Accordingly, we hold that BCO encapsulated with glycerin and gelatin is not a food additive. Because the FDA has not shown that BCO is adulterated or unsafe in any way, there is no basis to condemn the two drums at issue. If BCO is injurious to health, the statute requires the FDA to prove as much. Meanwhile, the Act's labeling requirements protect the consuming public to the extent mandated by Congress by enabling persons to weigh for themselves the benefits and risks of consuming BCO. The judgment of the district court is therefore
AFFIRMED.